



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Reports Clearance Officer at (301) 443-1129.

Comments are invited on: (a) the proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Organ Procurement and Transplantation Network and Scientific Registry of Transplant Recipients Data System (OMB No. 0915-0157) – [Revision]

Section 372 of the Public Health Service (PHS) Act requires that the Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). The OPTN, among other responsibilities, operates and maintains a national waiting list of individuals requiring organ transplants, maintains a computerized system for matching donor organs with transplant candidates on the waiting list, and operates a 24-hour system to facilitate matching organs with individuals included in the list.

Data for the OPTN data system are collected from transplant hospitals, organ procurement organizations, and tissue-typing laboratories. The information is used to indicate the disease severity of transplant candidates, to monitor compliance of member organizations with OPTN rules and requirements, and to report periodically on the clinical and scientific status of organ donation and transplantation in this country. Data are used to develop transplant, donation and allocation policies, to determine if institutional members are complying with policy, to determine member specific performance, to ensure patient safety and to fulfill the requirements of the OPTN Final Rule. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and others for evaluation, research, patient information, and other important purposes.

The OPTN is recommending addition of a new Liver Explant Pathology form to the OPTN data system. This new form was developed by the OPTN Liver and Intestinal Organ Transplantation Committee and will be used to collect pathology data on liver transplant recipients who received

waitlist exception points as a result of a diagnosis of hepatocellular carcinoma. Existing OPTN policy requires submission of post-transplant pathology reports by fax transmission, and the proposed form will provide standardized collection of this already-required information.

There are also minor revisions to the existing data collection forms; the added fields were inadvertently left off of the forms at the time of the initial submission. Several of these fields are “read only” and are included on the forms for information purposes only. One field is proposed to be removed as it represented duplicative information.

The annual estimate of burden is as follows:

Form	Number of Respondents	Responses per Respondents	Total Responses	Hours per Response	Total Burden Hours
Deceased Donor Registration	58	228	13,224	0.7500	9918.00
Death Referral Data	58	12	696	10.0000	6,960.00
Death Notification Referral – Eligible	58	145	8410	0.5000	4205.00
Death Notification Referral – Imminent	58	124	7192	0.5000	3596.00
Living Donor Registration	311	23	7153	0.6500	4649.45
Living Donor Follow-up	311	78	24,258	0.5000	12,129.00
Donor Histocompatibility	158	94	14,852	0.1000	1,485.20
Recipient Histocompatibility	158	171	27,018	0.2000	5,403.60
Heart Candidate Registration	131	27	3,537	0.5000	1,768.50
Lung Candidate Registration	66	41	2706	0.5000	1353.00
Heart/Lung Candidate Registration	50	1	50	0.5000	25.00
Thoracic Registration	131	34	4454	0.7500	3340.50
Thoracic Follow-up	131	277	36,287	0.6500	23,586.55
Kidney Candidate Registration	239	154	36,806	0.5000	18,403.00
Kidney Registration	239	72	17,208	0.7500	12,906.00
Kidney Follow-up *	239	693	165,627	0.5500	91,094.85
Liver Candidate Registration	132	98	12,936	0.5000	6,468.00
Liver Registration	132	48	6,336	0.6500	4,118.4
Liver Explant Pathology	132	11	1,452	0.3400	493.68
Liver Follow-up	132	459	60,588	0.5000	30,294.00

Kidney/Pancreas Candidate Registration	144	11	1,584	0.5000	792.00
Kidney/Pancreas Registration	144	6	864	0.9000	777.60
Kidney/Pancreas Follow-up	144	75	10,800	0.8500	9180.00
Pancreas Candidate Registration	144	4	576	0.5000	288.00
Pancreas Islet Candidate Registration	23	5	115	0.5000	57.50
Pancreas Registration	144	2	288	0.7500	216.00
Pancreas Follow-up	144	23	3312	0.6500	2152.80
Intestine Candidate Registration	43	5	215	0.5000	107.50
Intestine Registration	43	3	129	0.9000	116.10
Intestine Follow-up	43	25	1075	0.8500	913.75
Post Transplant Malignancy	689	11	7579	0.2000	1515.80
Total *Includes an estimated 2,430 kidney transplant patients transplanted prior to the initiation of the data system.	905		478,270		258,314.83

Email comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 23, 2011

Reva Harris

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